

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
No. 5:10-MD-1500-H(3)

SEPRACOR, INC., <u>et al.</u> ,)	
Plaintiffs,)	
)	
v.)	Western Division
)	No. 5:08-CV-179-H(3)
SYNTHON PHARMACEUTICALS, INC.,)	
<u>et al.</u> ,)	
Defendants.)	
_____)	
)	
SEPRACOR, INC., <u>et al.</u> ,)	
Plaintiffs,)	
)	
v.)	Eastern Division
)	No. 4:08-CV-89-H(3)
)	
SANDOZ, INC.,)	
Defendant.)	
_____)	

ORDER

These consolidated actions are before the court on the memorandum and recommendation ("M&R") of United States Magistrate Judge William A. Webb concerning the proper construction of disputed claim terms in U.S. Patent No. 5,698,558. (Mem. & Recommendation dated Sept. 8, 2010 [DE #235]). Plaintiffs have filed objections to the M&R, and defendants have responded. Plaintiffs have also filed a motion for leave to file a reply, to which the Synthon defendants¹

¹"The Synthon defendants" refers to Synthon Pharmaceuticals, Inc., Synthon Laboratories, Inc., Synthon Holding B.V., and Synthon B.V., who are defendants in the action styled as

object. The time for further filings has expired, and this matter is ripe for adjudication.

STATEMENT OF THE CASE

Sepracor, Inc. ("Sepracor"), together with UCB, S.A., and UCB, Inc. ("UCB") brought these actions against defendants for alleged infringement of U.S. Patent No. 5,698,558 ("the '558 patent"), entitled "Methods for Treating Allergic Disorders Using Optically Pure (-) Cetirizine." The '558 patent is assigned to Sepracor and exclusively licensed to UCB for the production of XYZAL®, a prescription antihistamine approved by the United States Food and Drug Administration ("FDA") for the treatment of seasonal and perennial allergic rhinitis. Each of the defendants has filed an Abbreviated New Drug Application seeking FDA approval to market a generic version of XYZAL® prior to expiration of the '558 patent. After extensive briefing by the parties and a hearing held on May 24, 2010, Magistrate Judge William A. Webb issued a thorough M&R construing two of the '558 patent terms.

COURT'S DISCUSSION

I. Plaintiffs' Motion for Leave to File Reply

Plaintiffs have filed a motion for leave to file a reply in support of its objections to Judge Webb's M&R concerning claim

construction. Plaintiffs' motion is GRANTED, and the court will consider plaintiffs' proposed reply memorandum, which was filed as an attachment to plaintiffs' motion on October 27, 2010 [DE #265-1].

II. Memorandum & Recommendation

A. Standard of Review

The district court reviews de novo those portions of the magistrate judge's report to which proper objection has been made. 28 U.S.C. § 636(b)(1); Fed. R. Civ. P. 72(b)(3). Upon review, a district judge may accept, reject, or modify the proposed findings or recommendations. Additionally, a district judge may receive further evidence or return the matter to the magistrate judge with instructions. Id.

B. Plaintiffs' Objections to the M&R

Plaintiffs object to Judge Webb's recommended construction of the term "sedation" as used in claim 2 of the '558 patent.² Plaintiffs contend that "sedation" refers to symptoms of

²Claim 2 reads as follows:

A method of treating the symptoms of seasonal and perennial allergic rhinitis in a human, while avoiding the concomitant liability of sedation associated with racemic cetirizine, which comprises administering to a human in need of such symptomatic relief therapy an amount of (-) cetirizine, or a pharmaceutically acceptable salt thereof, substantially free of its (+) stereoisomer, said amount being sufficient to alleviate or palliate said allergic rhinitis but insufficient to cause said sedation.

drowsiness (i.e. somnolence) and impairment (i.e. decreased mental abilities) and that Judge Webb erred in construing "sedation" to mean "central nervous system impairment." More specifically, plaintiffs argue that Judge Webb erred (1) by finding that "sedation" has no ordinary meaning; (2) by alternatively determining that the patentee disclaimed the ordinary meaning during prosecution of the claim; and (3) by recommending that "sedation" be construed to exclude somnolence.

Plaintiffs rely, in large part, upon an article referenced in the patent specification concerning cetirizine. See Deborah M. Campoli-Richards, Micaela M.-T. Buckley & Andrew Fitton, Cetirizine: A Review of its Pharmacological Properties and Clinical Potential in Allergic Rhinitis, Pollen-Induced Asthma, and Chronic Urticaria, Drugs 40(5): 762-81 (1990) ("Campoli-Richards article"). In this article, it is stated:

While CNS [central nervous system] effects are well recognized as being associated with classic H₁-receptor antagonist therapy, there appears to be no general agreement in the published literature on the meaning of "sedation" as applied to antihistamines. Subjective reports of "drowsiness" by patients in clinical trials may not correlate with objective measures of cognitive or psychomotor function. Most researchers appear to include measures of "drowsiness" together with parameters of cognitive impairment, or regard both effects as part of a continuum of CNS effects (see Gengo & Gabos 1987 for discussion). There are clinical reasons for maintaining a distinction: the occurrence of drowsiness may not necessarily prohibit use of an antihistamine during the day, whereas impairment of, for example, reaction times or eye-hand coordination would clearly limit its

use. Thus, lack of concordance in definition of relevant terms may to some extent hamper interpretation of studies investigating CNS effects.

Id. at 771. Plaintiffs maintain that the Campoli-Richards article, as well as the other intrinsic and extrinsic evidence in this case, establishes that most researchers consider drowsiness and cognitive impairment both to be part of "sedation" generally.

Plaintiffs further object to Judge Webb's alternate determination that the '558 patent had disclaimed somnolence as part of "sedation." Plaintiffs acknowledge that the specification of the '558 patent refers to "sedation" at times and to "sedation and somnolence" at others. However, plaintiffs assert there is no indication, much less a clear showing, that the patentee intended to apply different meanings to these two terms.

Following a thorough review of the M&R, the briefs submitted by the parties and the record in this case, the court adopts the recommendation of the magistrate judge. For the reasons stated in the M&R, "sedation" is construed to mean "central nervous system impairment,"³ and the phrase "said amount

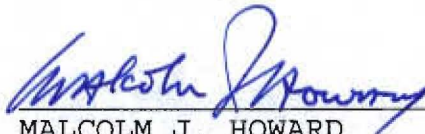
³Plaintiffs object to Judge Webb's use of the term "central nervous system impairment," arguing that he has not provided any definition of that term. Presumably, this objection is based upon plaintiffs' position that somnolence and cognitive impairment are part of a "continuum of central nervous system effects." While there does not appear to be any serious dispute

being sufficient to alleviate or palliate said allergic rhinitis but insufficient to cause said sedation" is construed to mean "an amount of (-) cetirizine, or a pharmaceutically acceptable salt thereof, that is sufficient to provide relief from the symptoms of allergic rhinitis but in an amount that does not cause the same degree of sedation caused by a therapeutically equivalent amount of racemic cetirizine."⁴

CONCLUSION

For the foregoing reasons, the court GRANTS plaintiffs' motion for leave to file a reply [DE #265] and ADOPTS the recommendation of the magistrate judge [DE #235] concerning the construction of claim 2 of the '558 patent.

This 18TH day of January 2011.



MALCOLM J. HOWARD
Senior United States District Judge

At Greenville, NC
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about Judge Webb's intended meaning, the court construes "central nervous system impairment" to exclude somnolence.

⁴Neither of the parties objected to Judge Webb's recommendation as to the construction of this phrase.